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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,469	10/15/2004	Yasuo Suzuki	2004-1390A	8950

513 7590 05/05/2006

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EXAMINER

KHARE, DEVESH

ART UNIT PAPER NUMBER

1623

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/506,469

Applicant(s)

SUZUKI ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/03/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

This application is a 371 of PCT/JP03/02338 filed 02/28/2003 which claims foreign priority to Japanese Application no. 2002-057909 filed 03/04/2002 under 35 U.S.C. 119 (a)- (d). The certified copy of the priority document has been filed with the PCT application. It is noted that PCT/JP03/02338 and the Japanese applications are in Japanese. Claims 1-10 have been cancelled and new claims 11-20 have been added by the preliminary amendment dated 09/03/2004.

An action on the merits of claims 11-20 is contained herein below.

Minor objections

Claims 11-20 are objected to because of the following informalities:

- (1) In claims 11-20, the use of term "novel" is improper. The term "novel" should be deleted.
 - (2) In claims 11, 15 and 16, the term "among" is improper Markush terminology. The term "among" should be deleted.
 - (3) In claim 20, the recitation "at least the" should be changed to "at least one of the".
- Appropriate correction is required.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-20 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claims 11,15 and 16 are vague and indefinite for setting forth substituents of formulae (I), (II) and (III) in parenthesis. It is unclear if the substituents described in the parenthesis are intended to be part of the claim.

(B) In claims 11,15 and 16, formulae (I), (II) and (III), in the absence of the identity of the type of bond or linkage between hex and hexNAc, render the claims indefinite wherein applicant fails to articulate the identity of the type of bond or linkage, requisite to identify the linkages such as type I (1-3 linkage) or type II (1-4 linkage) or 1-6 linkage between hex and hexNAc in a sialo-sugar molecule.

(C) In claims 11,15 and 16, the recitations "may be" or "may have" render these claims indefinite since the recitation "may be" or "may have" render the uncertainty and clarity of the claims. The applicant is deemed uncertain as to his/her intention by reciting, "the amido group may be chemically modified" and "R may have a substituent". Thus claims herein are indefinite as to the recitation "may be" or "may have" encompassed thereby.

Art Unit: 1623

(D) In claims 11,15 and 16 in the absence of the specific moieties intended to effectuate modification of "R" by a "substituent" or attachment to the chemical core claimed, the term "substituent" renders the claims indefinite wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution of "R", requisite to identifying the compound of matter claimed.

(E) Claims 11,15 and 16 recite, "R represents a substrate selected from a hydrogen atom, a hydrocarbon chain, a sugar chain, a lipid, a protein and a synthetic polymer", it is unclear what is the identity in terms of a name or formula for a hydrocarbon chain, a sugar chain, a lipid, a protein and a synthetic polymer. In absence of such name or formula, claims, which do not depict it, are indefinite. The phrases "a hydrocarbon chain"; "a sugar chain"; "a lipid"; "a protein"; and "a synthetic polymer" are not defined by the claims, the specification does not provide a standard for ascertaining their identities, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(F) In claims 12 and 17, the phrase "natural" is vague and indefinite with respect to the O-glycoside linkage. It is unclear whether the "natural O-glycoside linkage" is different from "O-glycoside linkage".

(G) In claims 14 and 19, the phrase "Se-glycoside linkage" is vague and indefinite with respect to the glycoside linkage. The term "Se-" is not defined by the claims, the specification does not provide a definition for ascertaining its expanded form, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Art Unit: 1623

(H) In claims 13 and 18, the phrase “chemically converted linkage” is vague and indefinite with respect to a linkage. The phrase “chemically converted linkage” is not defined by the claims, the specification does not provide a standard for ascertaining how a linkage is chemically converted, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Strecker et al (Eur. J. Biochem. 75, 391-403, 1977).

The applicants' claims are directed toward a branched sialo-sugar molecule represented by the formula (I) wherein the terminal sialic acid is linked to penultimate hexose in 2-6 and 2-3 linkages in combination with the sugar chain Hexose-N-acetylhexosamine and an antiviral agent thereof.

Strecker et al. disclose the structure of a branched sialyl-oligosaccharide wherein the terminal sialic acid is linked to penultimate galactose in 2-6 and 2-3 linkages in combination with the sugar chain Gal-GlcNAc (page 401, structure VI). Strecker et al.

also disclose the solubility of said sialyl-oligosaccharide in anionic chromatography buffers (page 394, fig. 2). Therefore Strecker et al's branched sialyl-oligosaccharide is encompassed by the applicants' claims.

With respect to the antiviral agent comprising the sialo-sugar molecule of formula (I) as an active ingredient of claim 20, the antiviral property of sialo-sugar molecule of formula (I) would be considered an inherent property of such sialo-sugar molecules.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (Prog. Lipid Res. Vol. 33, No.4, pp 429-457, 1994) in view of Masuda et al. (FEBS Letters 464, 71-74, 1999).

It is noted that claim 20 is rejected because claim 20 depends on claims 15 and 16.

Suzuki teaches that influenza A, B and C viruses specifically recognize and bind to a sugar chain containing a sialic acid (N-acetylneuraminic acid or NeuAc) in common of the gangliosides (see Introduction pages 430-431). Suzuki discloses that the virus bound most effectively to lacto-series gangliosides such as Neu5Ac α 2,3Gal-GlcNAc-ceramide type I and type II sugar chains (page 440, lines 1-7). Suzuki discloses the I-

Art Unit: 1623

Active ganglioside which shows high binding to influenza A virus (page 445, last structure in Table 1 and Table 5 on page 450) which renders the sialo-sugar molecule represented by formula I, II and III prima facie obvious. Furthermore, ganglioside such as GM1b, GD1a and GT1b having a sugar chain Neu5Ac α 2,3Gal-GalNAc-hex-ceramide shows moderate binding to influenza A and B viruses (Table 1, page 444). Suzuki also discloses binding reactivity of synthetic ganglioside analogs to human influenza A virus wherein terminal sialic acid is linked to penultimate galactose in thioglycoside linkage (page 447, Table 3 (g)). Suzuki discloses that these biologically active gangliosides may be used as anti-influenza drug or vaccine (page 431, line 6). The I-Active ganglioside (page 445) of the prior art differ from the applicant's that Suzuki does not explicitly teaches a ganglioside wherein terminal sialic acid is linked to penultimate galactose in 2-6 linkage however Suzuki discloses that human influenza B virus binds very strongly to 2-3 and 2-6 linkages, almost equally (page 451, 2nd para.).

Masuda et al. teach the binding reactivity of human influenza A viruses to four types of sialoglycolipids wherein the terminal sialyl linkage is varied (page 71, 2nd col. end of 2nd para.). Masuda et al. disclose that human influenza A virus recognized the Neu5Ac2-6Gal linkage more strongly than Neu5Ac2-3Gal (page 72, 2nd col. lines 1-9 and for glycolipid structures see Table 1 on page 73, first two structures).

Therefore, one of ordinary skill in the art would have found the applicants claimed sialo-sugar molecules represented by the formulae I, II and III wherein the terminal sialic acid is linked to penultimate galactose in 2-6 and 2-3 linkages in combination with the sugar chain Gal-GlcNAc or Gal-GalNAc and an antiviral agent thereof, to have been

Art Unit: 1623

obvious at the time the invention was made having the above cited references before him. Since Suzuki teaches the branched sialo-sugar molecules such as I-Active ganglioside wherein terminal sialic acid is linked to penultimate galactose in 2-3 linkage in combination with the sugar chain Gal-GlcNAc shows high binding to influenza A virus or the sugar chain Gal-GalNAc shows moderate binding to influenza viruses and Masuda et al. teach that human influenza A virus recognizes the Neu5Ac2-6Gal and Neu5Ac2-3Gal linkages, one skilled in the art would have a reasonable expectation for success in combining the teachings of these references to accomplish a sialo-sugar molecule having both Neu5Ac2-6Gal and Neu5Ac2-3Gal linkages in combination with the sugar chains such as Gal-GlcNAc or Gal-GalNAc.

The motivation is provided by Suzuki reference which discloses that these biologically active gangliosides can be used as anti-influenza drug and vaccine (page 431, line 6).

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0627. The official fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

Art Unit: 1623

more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Devesh

Devesh Khare, Ph.D., J.D.

Art Unit 1623

May 1, 2006